

AUG - 6 2004

K040637

## **SECTION 17: SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

### **17.1: ADMINISTRATIVE INFORMATION**

#### **Name and Address**

Submitted by: Cardiac Science Incorporated  
5474 Feltl Road  
Minnetonka, MN 55343

Contact Person: Kenneth F. Olson  
Telephone No.: 952-939-4181  
Facsimile No.: 952-939-4191  
Email: kolson@cardiacscience.com

Date Prepared: March 5, 2004

### **17.2: DEVICE INFORMATION**

Common or Usual Name: Automatic External Defibrillator

Trade Name: Powerheart® Automatic External Defibrillator  
G3Pro

### **17.3: DEVICE CLASSIFICATION**

Classification Name: Automated External Defibrillator  
21 CFR 870.5310 MKJ  
Device Class: III

### **17.4: DEVICE DESCRIPTION**

The Powerheart® AED G3Pro is a portable, battery-operated, semi-automatic, low power DC defibrillator. The device is designed to diagnose and monitor the patient's cardiac rhythm and deliver the shock energy as required. The Powerheart® AED G3Pro also has an ECG display and manual override for advanced users. The device in this submission is equivalent to the current Powerheart® AED and accessories in commercial distribution that was cleared under premarket 510(k) notifications K022929, K011901, K982710 and K031987. The reason for this premarket notification is to introduce the semi-automatic

#### **17.6: IDENTIFICATION OF PREDICATE DEVICE**

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Cardiac Science	Powerheart AED	K031987	07/30/2003
Philips Medical Systems	Heartstream FR2	K014157 K013425	01/17/2002 01/14/2002

#### **17.7: SUBSTANTIAL EQUIVALENCE**

The Powerheart® AED G3Pro covered by this submission is substantially equivalent to other legally marketed automatic external defibrillators. Specifically, the Powerheart® AED G3Pro that is the subject of this premarket notification is equivalent to the current Powerheart® AED G3 in commercial distribution with the exception of having the ECG display and manual override options. The Powerheart AED G3Pro is substantially equivalent to the ECG display and manual override features of the Philips Medical Systems Heartstream FR2 AED.

#### **17.8 PERFORMANCE TESTING**

The Powerheart® AED G3Pro is subjected to performance software and hardware evaluations in accordance with FDA guidelines and industry standards. The results of the testing showed that the device modifications had no affect on the safety or effectiveness of the device. The Powerheart® AED G3Pro was found to perform as intended.

#### **17.9 CONCLUSIONS**

Cardiac Science has demonstrated through its evaluation and testing of the Powerheart® AED G3Pro that the device is equivalent to the current Powerheart® AED and the Philips Medical Systems Heartstream FR2 AED. The proposed Powerheart® AED G3Pro is equivalent with respect to indications for use, technological characteristics, materials, and software algorithm as the current commercially distributed Powerheart® AED and the Heartstream AED. This notification contains all information required by 21 CFR 807.87.

A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 6 2004

Cardiac Science, Inc.  
c/o Mr. Kenneth f. Olson  
Chief Technology Officer  
5474 Feltl Road  
Minnetonka, MN 55343

Re: K040637

Trade Name: Powerheart<sup>®</sup> Automatic External Defibrillator G3Pro  
Regulation Number: 21 CFR 870.5310  
Regulation Name: Automatic External Defibrillator  
Regulatory Class: III (three)  
Product Code: NPN and MKJ  
Dated: June 22, 2004  
Received: June 23, 2004

Dear Mr Olson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

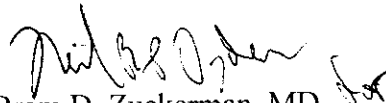
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Kenneth f. Olson

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", followed by a small "for" in cursive.

Bram D. Zuckerman, MD  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K040637

Device Name: Powerheart® Automatic External Defibrillator G3 Pro

### Indications For Use:

The Powerheart® AED G3 Pro, model 9300P, is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

When a patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the Powerheart AED G3 Pro should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. The therapy should not be delayed to determine the patient's exact age or weight.

At the discretion of emergency care personnel, the G3Pro with ECG display enabled can also be used with the Model 5111 ECG Patient Cable to display the rhythm of a responsive or breathing patient, regardless of age. The G3Pro and ECG Patient Cable system provides a non-diagnostic display for attended patient monitoring. While connected the G3Pro ECG Patient Cable, the G3Pro evaluates the patient's ECG and disables its shock capability.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

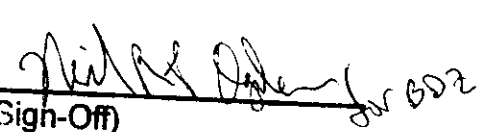
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K040637